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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/430,412	10/29/1999	PAUL ALBERT	2268UO-1	7273

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EXAMINER

HAYES, ROBERT CLINTON

ART UNIT PAPER NUMBER

1647

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/430,412

Applicant(s)

ALBERT ET AL.

Examiner

Robert C. Hayes, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 9-13 is/are pending in the application.
- 4a) Of the above claim(s) is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,9,10,12 and 13 is/are allowed.
- 6) ☒ Claim(s) 11 is/are rejected.
- 7) ☐ Claim(s) is/are objected to.
- 8) ☒ Claim(s) 1 and 9-13 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. .
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. <u> </u> |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u> </u> | 6) <input type="checkbox"/> Other: <u> </u> |

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DETAILED ACTION

Response to Amendment

1. The amendment filed 7/23/04 has been entered.

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because 37 CFR 1.821 (a)(2)(c-d) states that *each sequence disclosed must appear separately in the "Sequence listing" and in the text of the description and claims whenever described*. For example, the appropriate SEQ ID NOs must be recited in the figure legends for Figures 1 & 5 on pages 4-5 of the specification (e.g., position #s can be used as it relates to SEQ ID NO: 1 in Figure 5). Pages 3, 6 & 7 also need to be amended to recite the appropriate position in SEQ ID NO: 1. In other words, the corresponding positions as it relates to SEQ ID NO: 1 is required (e.g., as it relates to Figure 1's numbering). Pages 14 & 19 also need to be amended to indicate the appropriate SEQ ID NOs; especially since it is unclear if any SEQ ID NOs exist for these nucleotide sequences, as required.

Note that failure to respond to both the requirements for sequence compliance and the restriction requirement below will be held as *nonresponsive*, and may result in *abandonment* of this application.

2. Claims 1, 9-10 & 12-13 are allowed. However, it is suggested that amending claim 12 (third line) to "fully complementary to SEQ ID NO: 2 or said fragment thereof, wherein the DNA molecule forms..." would more accurately claim the instant invention.

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3. The rejection of claims 1-4 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is withdrawn due to the amendment or cancellation of the claims.

4. The rejection of claims 1-4 under 35 U.S.C. 112, first paragraph, for lack of written description is withdrawn due to the amendment or cancellation of the claims.

5. The rejection of claims 1-4 under 35 U.S.C. 112, first paragraph, for lack of enablement is withdrawn due to the amendment or cancellation of the claims.

6. The rejection of claims 2-4 under 35 U.S.C. 112, second paragraph, as being indefinite and/or incomplete is withdrawn due to the amendment and cancellation of the claims.

7. Applicants' arguments filed 7/23/04 have been considered but were not found persuasive.

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claim 11 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In particular, claim 11 is broader than base claim 1.

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10. Claim 11 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons made of record for claims 1-4 in Paper No: 20040415, and as follows.

As previously made of record, no written description is provided in the instant specification as to what structurally constitutes nucleotide sequences *comprising* unknown and undescribed promoter sequences, 5'- or 3'-flanking or enhancer or silencer regions, or any other undescribed genomic DNA sequences that “*comprise* positions 2420 to 2443 of SEQ ID NO:1”, which are further not limited to human “gene” sequences. Thus, one skilled in the art can not reasonably visualize or predict what critical nucleotide residues would structurally characterize the genus of polynucleotides that constitute such a mutated 5-HT1A receptor gene; thereby, not reasonably meeting the written description requirements under 35 U.S.C. 112, first paragraph, for the reasons previously made of record.

11. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is ambiguous whether a C-G substitution in SEQ ID NO: 1 is envisioned in dependent claim 11, since no such mutation is recited in claim 11, yet such a substitution is recited in base claim 1.

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12. Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Parks et al (IDS Ref #AF; 1996), for the reasons made of record for claims 1-4 in Paper No: 20040415, and as follows.

In summary, Parks et al. teach isolation of the human 5-HT1A receptor gene promoter, which "comprise positions 2420 to 2443 of SEQ ID NO: 1" (e.g., pg. 4420; Fig. 1).

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961. The fax phone number for this Group is (703) 872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert C. Hayes, Ph.D.
October 4, 2004

ROBERT C. HAYES, PH.D.
PATENT EXAMINER



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